DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Vanguard Medical Concepts, Inc.
c/o Ms. Heather Crawford, RAC
Director of Regulatory Affairs
5307 Great Oak Drive
Lakeland, FL 33815

Re: K012688 - Supplemental Validation Submission
Trade Name: See Enclosed List
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: II (two)
Product Code: NLH
Dated: August 13, 2001
Received: August 14, 2001

Dear Ms. Crawford:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on July 31, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K012688
Enclosure - List of devices (21 models)

(Bard Viking)

400004	400005	400006	400102
400091P	400044	400045	400046

(Bard Woven)

200066	200067	200068	200069
200201P	8567	200624	200728
006692P	002943P	200202	200472
006245P			

Indications for Use

510(k) Number: K012688

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012688

JUL 3 1 2002

K012688

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
(863) 683-8680, extension 228
(801) 327-3339 (facsimile)
mikes@safe-reuse.com

Date

August 13, 2001

Device

- Trade Names: Vanguard Reprocessed Diagnostic Electrophysiology Catheters
  ⇒ Bard Electrophysiology Diagnostic Electrophysiology Catheters
- Common Name: Diagnostic Electrophysiology (EP) Catheter
- Classification: 21 CFR 870.1220 – Class II – Electrode recording catheter or electrode recording probe
- Product Code DRF

Predicate Devices

Biosense Webster and Bard Electrophysiology legally marketed diagnostic EP catheters under various 510(k) premarket notifications.

Indications for Use

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

Continued on next page

K012688

510(k) Summary of Safety & Effectiveness, Continued

Contra-indications

- Patients with active systemic infection.
- Patients with prosthetic valves.
- Retrograde approach in patients with aortic valve replacement.
- Transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle patch.
- Diagnostic EP catheters are not intended for electrical ablation.

Device Description

Diagnostic electrophysiology catheters are constructed of a hollow polymer shaft approximately 92 to 125 cm in length that terminates with a hand piece or connector. A range of diameters is available; the most clinically utilized sizes are the 5 – 7 French. Various configurations of distal platinum alloy electrodes are wired to a proximal connector for bi-directional transmission of electrical signals (pacing and recording). The connector is attached to an interconnecting cable that interfaces with various standard types of sensing, recording, stimulation and pacing equipment. The catheters are available with various distal curves, either fixed or deflectable. This allows for remote manipulation of the distal tip segment that facilitates precise positioning of the electrode array.

In addition to a range of diameters, the catheters are also available in a variety of electrode configurations, connector compatibility and torque-transmitting properties that are selected by the clinician based on preference and/or indication. The shaft polymer is manufactured with additives (typically barium sulfate) that enhance the catheter's radiopacity to enable positioning under fluoroscopic guidance. No lumens of the catheters reprocessed by Vanguard are open to the patient bloodstream.

Vanguard receives previously used diagnostic EP catheters from healthcare facilities; cleans, inspects, tests, refurbishes, repackages and sterilizes the devices; and returns them to the healthcare facility.

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K012688

510(k) Summary of Safety & Effectiveness, Continued

Technological Characteristics	The Vanguard reprocessed diagnostic EP catheters are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.
Test Data	Cleaning, sterilization and packaging validations; and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard Reprocessed Diagnostic EP Catheters (Bard Woven Fixed Curve and Viking™ Fixed Curve catheters) are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.